2673. Misbranding of Stancrest Sulphur Bath Solution and Circulex Therapeutic Units (device). U. S. v. 24 Cans, etc. (F. D. C. No. 26583. Sample Nos. 14185–K, 14187–K.)

LIBEL FILED: March 22, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: The *Stancrest Sulphur Bath Solution* was shipped on or about October 27, 1948, by the Sulphur Products Co., Inc., from Greensburg, Pa., and the *Circulex Therapeutic Units* were shipped on or about August 28, 1948, by Barnett E. Laxer, from Buffalo, N. Y.

PRODUCT: 24 unlabeled gallon cans and 57 unlabeled quart cans and 4 labeled gallon cans and 17 labeled quart cans of *Stancrest Sulphur Bath Solution*, 500 *Stancrest Sulphur Bath Solution* labels, 23 *Circulex Therapeutic Units*, and 276 catalogs at Chicago, Ill., in possession of the Stanley Physical Therapy Equipment & Supply Co.

The unlabeled cans of the *Stancrest Sulphur Bath Solution* were to be labeled with the aforementioned labels at the time orders were received for the product. However, no labeling agreement such as is contemplated by the law and the regulations existed between the consignor and consignee. The catalogs were entitled "The Practical Physical Therapist February & March 1948 [or "January–February 1949"]" and were designed by the consignee for use in connection with the various products on sale by him.

Analysis showed that the *Stancrest Sulphur Bath Solution* consisted essentially of a lime-sulfur solution and that the device consisted of a metal case containing a motor, mounted off center, which produced a vibratory motion when operated.

LABEL, IN PART: "Stancrest Sulphur Bath Solution" and "Circulex Therapeutic Units."

NATURE OF CHARGE: *Stancrest Sulphur Bath Solution.* Misbranding (unlabeled cans), Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (e) (2), it was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient. Further misbranding (labeled cans), Section 502 (a), certain statements on the label of the article and in the catalogs were false and misleading since they represented and suggested that the article was effective in the treatment of arthritis and all types of skin disorders, whereas it was not effective for such purposes. The article was misbranded under Section 502 (a) while held for sale after shipment in interstate commerce.

Circulex Therapeutic Units. Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use. The device was misbranded under this section when introduced into and while in interstate commerce. Further misbranding, Section 502 (a), the following statements in the labeling of the device "Treating Spine, Rectum, Anus, Prostate, Vagina, and other pelvic organs, for relief of aches and pains in the back and shoulders, treating legs for * * * varicose veins and other ailments, treating * * * aching feet and legs" were false and misleading since the device was not effective in the treatment of the diseases and conditions stated and implied. The device was misbranded under this section while held for sale after shipment in interstate commerce.

DISPOSITION: June 14, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2674. Adulteration of isotonic solution of sodium chloride and distilled water. U. S. v. 228 Bottles, etc. (F. D. C. No. 26254. Sample Nos. 46890–K, 46891–K.)

LIBEL FILED: January 3, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about November 16, 1948, by Readyflask, Inc., from Lakewood, Ohio.

PRODUCT: 228 bottles of *isotonic solution of sodium chloride* and 356 bottles of *distilled water* at Buffalo, N. Y. Each bottle contained 50 cc. The products were packaged in flasks of a type intended for the administration of injections.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" and "Water for Injection," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standards since they were contaminated with undissolved material.

DISPOSITION: February 1, 1949. Default decree of condemnation and destruction.

2675. Adulteration of water for injection. U. S. v. 988 Vials * * *. (F. D. C. No. 26280. Sample No. 7856–K.)

LIBEL FILED: January 17, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about October 23, 1948, from Decatur, Ill.

PRODUCT: 988 100-cc. vials of *water for injection* at Buffalo, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 16, 1949. Default decree of condemnation and destruction.

2676. Adulteration of Hepafer Vitamin B_1. U. S. v. 1 Box * * *. (F. D. C. No. 26388. Sample No. 4849–K.)

LIBEL FILED: January 6, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about December 11, 1948, by Carlo Erba New York, Inc., from New York, N. Y.

PRODUCT: 1 box containing 72 ampuls of *Hepafer Vitamin B_1* at Springfield, Mass.

LABEL, IN PART: (Box) "Hepafer-Vitamin B_1 #2 * * * a sterile aqueous solution * * * Dosage and Administration: Intramuscularly"; (ampul) "Hepafer With Vitamin B_1 #2 * * * Intramuscular."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since the article purported to be and was represented as an aqueous solution intended for injection intramuscularly and was not suitable for such use. The